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PATENT APPLICATION

ATTORNEY DOCKET NO. 200401492-1

IN THE
UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Iddys D. Figueroa et al.	Confirmation No.: 3171
Application No.: 10/801,379	Examiner: E. Cameron
Filing Date: March 15, 2004	Group Art Unit: 1762

Title: APPLICATION OF A BIOACTIVE AGENT TO A DELIVERY SUBSTRATE

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Commissioner For Patents
PO Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF APPEAL BRIEF

Transmitted herewith is the Appeal Brief in this application with respect to the Notice of Appeal filed on February 6, 2007.

The fee for filing this Appeal Brief is (37 CFR 1.17(c)) $500.00.

(complete (a) or (b) as applicable)

The proceedings herein are for a patent application and the provisions of 37 CFR 1.136(a) apply.

☐ (a) Applicant petitions for an extension of time under 37 CFR 1.136 (fees: 37 CFR 1.17(a)-(d)) for the total number of months checked below:

☐ 1st Month $120	☐ 2nd Month $450	☐ 3rd Month $1020	☐ 4th Month $1590

☐ The extension fee has already been filed in this application.

☒ (b) Applicant believes that no extension of time is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

Please charge to Deposit Account 08-2025 the sum of $ 500. At any time during the pendency of this application, please charge any fees required or credit any over payment to Deposit Account 08-2025 pursuant to 37 CFR 1.25. Additionally please charge any fees to Deposit Account 08-2025 under 37 CFR 1.16 through 1.21 inclusive, and any other sections in Title 37 of the Code of Federal Regulations that may regulate fees. A duplicate copy of this sheet is enclosed.

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Respectfully submitted,
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of			Dated: April 6, 2007
IDDYS D. FIGUEROA, et al.			HP Docket No. 200401492-1
Serial No.	:	10/801,379	Examiner Erma C. Cameron
Filed	:	March 15, 2004	Group Art Unit 1762
For	:	APPLICATION OF A BIOACTIVE AGENT TO A DELIVERY SUBSTRATE	

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S i r :

BRIEF OF APPELLANTS

I. REAL PARTY IN INTEREST

The real party in interest is Hewlett-Packard Development Company, LP, a limited partnership established under the laws of the State of Texas and having a principal place of business at 20555 S.H. 249 Houston, TX 77070, U.S.A. (hereinafter "HPDC"). HPDC is a Texas limited partnership and is a wholly-owned affiliate of Hewlett-Packard Company, a Delaware Corporation, headquartered in Palo Alto, CA. The general or managing partner of HPDC is HPQ Holdings, LLC.

II. RELATED APPEALS AND INTERFERENCES

There are no known related appeals or interferences.

III. STATUS OF CLAIMS

The present application was filed on March 15, 2004 with original claims 1-24. In their response dated December 21, 2005, Appellants canceled claims 8-24. In their response dated June 2, 2006, Appellants amended claim 1, and added new claims 25-29. In their response dated October 5, 2006, Appellants amended claim 25.

Claims 1-7, and 27-29 as amended in the response dated October 5, 2006 are the claims at issue in this appeal. Claims 1-7 and 27-29 stand rejected.

IV. STATUS OF AMENDMENTS

No amendments have been made subsequent to the Office action dated October 5, 2006.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The summary is set forth in exemplary embodiments. Discussions of selected elements and recitations of claimed subject matter can be found at least at the cited locations in the specifications and drawings. The claims of the present application are directed to methods of controlling dissolution rates of bioactive agents, as generally described at page 4, line 23 to page 21, line 13 of the specification, and as set out in Figures 1-10. More particularly, the claims are directed to the application of bioactive agents to a substrate in order to achieve a target dissolution rate of the bioactive agent by forming dots having a desired dot topography, as generally discussed at page 11, line 11 to page 21, line 3. More particularly, the relationship between dot topography and target dissolution rate, and the application parameters that may be used to

influence dot topography, are discussed at page 18, line 19 to page 21, line 3; and in Figures 8 and 9.

Independent Claim 1 is directed to a method of controlling a dissolution rate of a bioactive agent, as shown in flowchart 100 of Fig. 10 and discussed at page 21, lines 4-11. The claimed method includes identifying a target dissolution rate, selecting a desired dot topography corresponding to the target dissolution rate at 102 in Fig. 10, and applying a bioactive agent to a delivery substrate to form dots having the desired dot topography on the delivery substrate at 104 in Fig. 10.

Independent claim 26 is directed to a method of controlling a dissolution rate of a bioactive agent, as shown in flowchart 100 of Fig. 10 and discussed at page 21, lines 4-11. The claimed method includes identifying a target dissolution rate, selecting a dot topography based on the target dissolution rate at 102 in Fig. 10, and applying a bioactive agent to a delivery substrate to form dots having the selected dot topography at 103 in Fig. 10, thereby achieving the identified target dissolution rate.

Independent claim 29 is directed to a method of controlling a dissolution rate of a bioactive agent, as shown in flowchart 100 of Fig. 10 and discussed at page 21, lines 4-11. The claimed method includes identifying a target dissolution rate, selecting a desired dot topography from a plurality of possible dot topographies, where the desired dot topography is selected to produce dots with a topographical surface area that corresponds to the target dissolution rate at 102 in Fig. 10, and applying a bioactive agent to a delivery substrate based on application parameters that are configured to form dots having the desired dot topography at 103 in Fig. 10.

VI. GROUNDS OF REJECTION

In the Office action dated December 19, 2007, claims 1-7 and 25-29 were rejected. More specifically,

- Claims 1-2, 4-7, and 25-29 are rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Voss et al. (U.S. Patent No. 4,322,449);
- Claim 3 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Voss et al. (U.S. Patent No. 4,322,449) as applied above, in view of Voges (U.S. Patent No. 5,894,841).

VII. ARGUMENT

Rejections under 35 U.S.C. §§ 102 and/or 103

The Examiner has rejected claims 1-2, 4-7, and 25-29 under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Voss et al. (U.S. Patent No. 4,322,449). Appellants respectfully disagree that the Voss et al. reference discloses each and every element of the rejected claims, and suggests that Voss et al. fails to establish a *prima face* case of obviousness.

Independent claims 1, 26, and 29 include the elements of "identifying a target dissolution rate," and the selection of a desired dot topography for the applied dots of bioactive agent, where the dot typography is selected to correspond to the target dissolution rate. In order to anticipate a claim under 35 U.S.C. § 102, a reference must teach each and every element as set forth in the claim. That is, the identical invention must be shown in as complete detail as is contained in the patent claim. *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (CAFC 1989). There is no disclosure whatsoever in Voss et al. of identifying a target dissolution rate, or in

fact *any* disclosure of dissolution rates. Additionally, Voss et al. fails to discuss the importance of dot shape and/or topography on the dissolution rate of the applied pharmaceutical. As a result, Appellants suggest that Voss et al. must necessarily fail to disclose each and every element as set forth in the claim.

Voss et al. specifically discloses the control of various parameters of the application of pharmaceuticals onto a pharmaceutical carrier using a piezoelectric dosing system. In particular, Voss et al. discuss the particular parameters that may be used in order to control the dosage of a pharmaceutical applied to a carrier at column 4, lines 13-26 of the reference:

> The dosing may be controlled by one or more of the following parameters:
> (a) the diameter of the outlet opening of the nozzle channels;
> (b) the voltage applied to the piezoelectric oscillator;
> (c) the droplet frequency;
> (d) the number of nozzle channels;
> (e) the stroke intensity of the tubular or planar oscillator used;
> (f) the active substance concentration of the solution or suspension; and
> (g) the number of dots of active substance per pharmaceutical carrier.

Voss et al. stress that their disclosed method permits "extremely precise dosing of active pharmaceutical ingredients onto pharmaceutical carriers" (col. 1, lines 62-66), and that "exact dosing of these active substances is of special importance" (col. 1, lines 46-51).

While Appellants agree that precise dosing is important, they respectfully suggest that the dissolution rate of the pharmaceutical is also important, and distinct from

dosage. As indicated in the specification at page 3, line 3 to page 4, line 2, control of the release profile of a pharmaceutical can be highly advantageous. For example, the effective duration of a medication may be extended by decreasing a dissolution rate, or the efficacy of a medication can be increased by increasing the dissolution rate. These, and other related effects, are *distinct* from simple precision in controlling the dosage of the medication.

The Examiner suggests that "controlling the dot pattern, the size or shape of the dot, or the consistency of the size of the dots will inherently provide control over the dissolution rate", and Voss et al. inherently discloses a method of applying a bioactive substance so as to arrive at a target dissolution rate. More particularly, the Examiner suggests that it would have been *inherent* for one of ordinary skill in the art to identify, in addition to a desired target dose, a target dissolution rate.

Appellants respectfully disagree. It has been established that the recitation of a newly discovered function or property, where that function or property is inherently possessed by things in the prior art, does not confer novelty on such claimed subject matter. However, that is not the fact pattern of the present rejection. Voss et al. is silent with respect to the selection of a target dissolution rate, and is silent with respect to what characteristics of dot topography may confer a greater or lesser dissolution rate on applied pharmaceuticals. Furthermore, both the selection of a dissolution rate and the selection of a dot topography based on that dissolution rate are elements of claims 1 and 29 that involve an intent to achieve the target dissolution rate. These conscious and affirmative selections *cannot* be disclosed through mere inherency.

As stated by the Court of Appeals for the Federal Circuit, "inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Continental Can Co. USA, Inc. v. Monsanto Co.,* 948 F.2d 1264, 20 U.S.P.Q.2d 1256 (Fed. Cir. 1991). That is, even if modification of the Voss et al. parameters *might* change the resulting dissolution rate is still not sufficient to establish anticipation.

Appellants respectfully suggest that claims 1 and 29 are not anticipated by the Voss et al. reference, and therefore request the withdrawal of the rejection of claims 1-2, 4-7, and 25-29 under 35 U.S.C. § 102(b).

Alternatively, the Examiner suggests it would have been obvious to one of ordinary skill in the art to select a target dissolution rate to be achieved by the patterns of Voss to ensure the safe and effective administration of drugs to patients. Appellants respectfully disagree, and suggest that the Examiner has failed to establish the *prima facie* obviousness of the rejected claims.

In order to establish *prima facie* obviousness, the Examiner must satisfy three criteria. There must be some suggestion or motivation present in the prior art to modify the reference or to combine the reference teachings. The prior art must also provide a reasonable expectation of success. Additionally, the prior art references must teach or suggest each and every element of the claim.

As discussed above, Voss et al. fails disclose each and every element of the rejected claims, for example the elements "identifying a target dissolution rate" and "selecting a desired dot topography", where the desired dot topography corresponds to the target dissolution rate.

Moreover, the Examiner has failed to provide a sufficient suggestion or motivation in the prior art to modify the reference teachings so as to arrive at the claimed invention, by suggesting that it would have been "inherent for one of ordinary skill in the art to identify, in addition to a desired target dose, a target dissolution rate" (Final Office action at page 3, lines 16-18). The Examiner suggests that, as medical professionals would have been aware of the importance of dissolution rate in administering medication, one of ordinary skill would have placed the drops of bioactive agent in such a way as to achieve a target dissolution rate via a particular dot topography.

The criteria for satisfying the requirements of 35 U.S.C. § 103 are intentionally strenuously high, precisely to prevent the trivial application of hindsight reconstruction of an otherwise patentable invention. For this reason obviousness can only properly be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is a specific teaching, suggestion, or motivation to do so. In the present rejection, the Examiner is merely asserting that such motivation must necessarily exist. Such an assertion is insufficient for establishing the *prima facie* obviousness of the rejected claims.

Furthermore, the Examiner may not simply rely upon the level of skill in the art in order to provide the necessary suggestion to combine or modify the cited references. Merely because such a modification would have been "well within the ordinary skill of the art at the time of the invention'" is not sufficient to establish *prima facie* obviousness (see MPEP § 2143.01).

In the absence of a disclosure of each and every element of the rejected claims in the cited reference, or the identification of an appropriate suggestion or motivation to modify the teachings of the reference so as to arrive at the claimed invention, Appellants suggest the Examiner has failed to establish the *prima facie* obviousness of claims 1 and 29.

In view of the arguments present above, Appellants suggest that independent claims 1, 26, and 29 are neither anticipated nor rendered obvious by the cited reference. Appellants respectfully request the withdrawal of the rejection of claims 1, 26, and 29 under 35 U.S.C. § 102(b) and in the alternative, under 35 U.S.C. § 103(a).

As claims 2, 4-7, and 25-28 depend directly or indirectly from claims 1 and 26, Appellants suggest they are similarly not anticipated or rendered obvious by Voss et al.

Claim 25 recites the selection of a textured dot topography to increase the dissolution rate of the bioactive agent, or selection of a smooth dot topography to decrease the dissolution rate of the bioactive agent. The Voss et al. reference fails to disclose the effect of dot surface topography on pharmaceutical dissolution rates, and fails to suggest the manipulation of dot surface texture to achieve a targeted dissolution

rate. Appellants therefore suggest that claim 25 is additionally novel and unobvious over Voss et al.

Claim 27 recites the selection of a dot topography that includes a selected crystal morphology that corresponds to the target dissolution rate. The Voss et al. reference fails to disclose the effect of crystal morphology on pharmaceutical dissolution rates, and fails to suggest the manipulation of crystal morphology to achieve a targeted dissolution rate. Appellants therefore suggest that claim 27 is additionally novel and unobvious over Voss et al.

The Examiner has rejected claim 3 under 35 U.S.C. § 103(a) as being unpatentable over Voss et al. (U.S. Patent No. 4,322,440) as applied above, in view of Voges (U.S. Patent No. 5,894,841).

As discussed above, Appellants suggest that Voss et al. fails to disclose each and every element of independent claim 1, and fails to provide a suggestion or motivation to modify the teachings of Voss et al. so as to arrive at the claimed invention.

The Voges reference is directed to a hand-held dispenser of droplets of medication for inhalation. As discussed in their specification, the parameters that may be varied in order to arrive at a selected dot topography and therefore a target dissolution rate include amorphous or crystal morphologies of deposited dots, shape of deposited dots, dot spacing, and dot overlap, among others. None of these parameters are relevant to the dispenser of Voges, which dispenses liquid droplets for inhalation. Similar to the apparatus of Voss et al., the medication *dosage* may be carefully

controlled by varying the number of droplets applied, but the reference provides no suggestion as to how to modify the medication dissolution rate.

Furthermore, if the apparatus of Voges were modified so as to print medication onto a delivery substrate, as recited in the rejected claims, the modification would destroy the utility of the Voges dispenser for inhalation therapy. Where a modification of the prior art would destroy its stated utility, there can be no suggestion or motivation to modify that reference, as suggested by the Examiner.

In view of the above remarks, Appellants respectfully suggest that claim 3 is not rendered unpatentable under 35 U.S.C. § 103 over Voss et al., in view of Voges. Appellants therefore request the withdrawal of the rejection of those claims under 35 U.S.C. § 103(a).

As discussed above, in the absence of a disclosure of each and every element of the rejected claims, the absence of specific motivation or suggestion in the cited reference to combine or modify the reference teachings as suggested by the Examiner, and in view of the teaching of the cited references. Claims 1-7 and 25-29 are neither anticipated under 35 U.S.C. § 102(b) nor rendered obvious under 35 U.S.C. § 103. Appellants therefore respectfully request the withdrawal of the rejection of those claims.

VIII. CLAIMS APPENDIX

1. (Previously Presented) A method of controlling a dissolution rate of a bioactive agent, the method comprising:

identifying a target dissolution rate;

selecting a desired dot topography corresponding to the target dissolution rate; and

applying a bioactive agent to a delivery substrate to form dots having the desired dot topography on the delivery substrate.

2. (Original) The method of claim 1, wherein a dot topography of each of the dots is characterized by a standard deviation of topographical surface area that is less than approximately 15% of a mean topographical surface area.

3. (Original) The method of claim 1, wherein applying the bioactive agent to the delivery substrate includes heating a solution carrying the bioactive agent with a thermal ejection element.

4. (Original) The method of claim 1, wherein applying the bioactive agent to the delivery substrate includes displacing a solution carrying the bioactive agent with a piezoelectric ejection element.

5. (Original) The method of claim 1, wherein applying the bioactive agent to the delivery substrate includes ejecting drops of solvent carrying the bioactive agent in a concentration based on the desired dot topography.

6. (Original) The method of claim 1, wherein applying the bioactive agent to the delivery substrate includes ejecting drops of solvent carrying the bioactive agent, wherein the drops have a drop volume based on the desired dot topography.

7. (Original) The method of claim 1, wherein applying the bioactive agent to the delivery substrate includes ejecting drops of solvent carrying the bioactive agent onto the delivery substrate and drying the solvent based on the desired dot topography.

25. (Previously Presented) The method of claim 1, wherein selecting the desired dot topography includes selecting a textured topography to increase the dissolution rate of the bioactive agent or selecting a smooth topography to decrease the dissolution rate of the bioactive agent.

26. (Previously Presented) A method of controlling dissolution rate of a bioactive agent, the method comprising:

identifying a target dissolution rate;

selecting a dot topography based on the target dissolution rate; and

applying a bioactive agent to a delivery substrate to form dots having the selected dot topography, thereby achieving the identified target dissolution rate.

27. (Previously Presented) The method of claim 26, wherein selecting the dot topography includes selecting a crystal morphology corresponding to the target dissolution rate.

28. (Previously Presented) The method of claim 27, wherein applying the bioactive agent includes adjusting one or more application parameters from a group of application parameters consisting of solvent formulation, drop size, removal rates and crystal templates, to achieve the selected crystal morphology.

29. (Previously Presented) A method of controlling dissolution rate of a bioactive agent, the method comprising:

identifying a target dissolution rate;

selecting a desired dot topography from a plurality of possible dot topographies, the desired dot topography being selected to produce dots with topographical surface area corresponding to the target dissolution rate; and

applying a bioactive agent to a delivery substrate based on application parameters configured to form dots having the desired dot topography.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on April 6, 2007.

Christie A. Doolittle